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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,128

03/15/2004

Bradley J. Glenn

04005.101

3404

41689

7590

03/06/2008

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

03/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,128	Applicant(s) GLENN ET AL.	
	Examiner JAVIER G. BLANCO	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 46-53 is/are pending in the application.
- 4a) Of the above claim(s) 4-6,8,9,13,16,18-22,46-49 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 10-12, 14, 15, 17, 50, 51, and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In view of the Appeal Brief filed on December 7, 2007, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 7, 11, 12, 17, 50, and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Petit (WO 2002/09625 A1). For English translation, see US PG Pub No 2004/0082953 A1.

Referring to Figures 1-12 (particularly Figure 3), Petit discloses a implant (1) *for location* within an intervertebral space between a pair of adjacent vertebrae, the implant comprising a helical spring (3) having a plurality of turns (helical turns 4) about a center line (indicated by "A" in Figure 3); said helical spring *adapted to be located* with said center line extending within a plane located between the two vertebrae (clearly seen in the Figures 8-12); said helical spring *adapted to encounter* compression loads transverse to said center line; said helical spring *adapted to flex* in a direction transverse to said center line responsive to said transverse loads; at least one of said turns *adapted to have* a turn height of at least half of a height of the space between the two vertebrae (the "a height of the space between the two vertebrae" is patient dependent); and said center line being non-circular (see Figure 3) when said helical spring is unloaded and at body temperature. As seen in Figure 3, said center line is substantially linear. Further, as seen in Figure 3 (and described in paragraphs 0015, 0031, and 0053 of the US PG Publication) said implant has an ellipsoidal cross-section, wherein said helical spring is shorter, in a direction perpendicular to said center line and *adapted to be oriented vertically* when implanted, than it is wide; said width defined as being in a direction perpendicular to said center line and *adapted to be oriented horizontally when implanted*.

The intended use recitations carry no patentable weight in the absence of any distinguishing structure. Also, claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531

(CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

4. Claims 1-3, 7, 11, 12, 17, 50, and 51 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bagby (US 5,263,953 A).

Referring to Figures 1-10, Bagby discloses a implant (1) *for location* within an intervertebral space between a pair of adjacent vertebrae, the implant comprising a helical spring (10) having a plurality of turns about a center line; said helical spring *adapted to be located* with said center line extending within a plane located between the two vertebrae (clearly seen in Figures 3 and 5-10); said helical spring *adapted to encounter* compression loads transverse to said center line (see column 6, lines 8-10; column 9, lines 11-15); said helical spring *adapted to flex* in a direction transverse to said center line responsive to said transverse loads (see column 6, lines 8-10; column 9, lines 11-15); at least one of said turns *adapted to have* a turn height of at least half of a height of the space between the two vertebrae (the “a height of the space between the two vertebrae” is patient dependent); and said center line being non-circular when said helical spring is unloaded and at body temperature. As seen in the Figures, said center line is substantially linear. Bagby discloses (see column 5, lines 13-19) said implant as having an ellipsoidal cross-section, wherein said helical spring is shorter, in a direction perpendicular to said center line and *adapted to be oriented vertically* when implanted, than it is wide; said width

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defined as being in a direction perpendicular to said center line and *adapted to be oriented horizontally when implanted*. It is noted Bagby discloses turns adjacent a middle of said spring have a height greater than turns of said spring adjacent and end of said helical spring (see column 5, lines 31-38).

The intended use recitations carry no patentable weight in the absence of any distinguishing structure. Also, claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagby (US 5,263,953 A) in view of Lambrecht et al. (US 6,508,839 B1) or Perren et al. (US 6,019,793 A).

Bagby discloses the invention as claimed in claims 1-3, 7, 11, 12, 15, 17, 50, 51, and 53 (see 102(b) rejection above). Although Bagby discloses the helical coil as made of metal, and as

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compressible and expandable (see, for example, column 11), he/she did not particularly disclose the helical spring as formed of a nickel titanium alloy, and adapted to be placed within a delivery cannula. However, said subject matter is well known in the art.

For example, Lambrecht et al. disclose a coiled spring (see Figures 38-41) formed of a self expanding material such as nickel titanium alloy in order to compress and fit said coiled spring within a delivery cannula (e.g., reducing the overall volume of the spring), simplifying insertion through a narrow cannula (see column 21, lines 43-50). Said nickel titanium alloy has a martensite phase and an austenite phase. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a spring formed of a nickel titanium alloy, as taught by Lambrecht et al., with the helical coil of Bagby, in order to compress and fit said coiled spring within a delivery cannula (e.g., reducing the overall volume of the spring), simplifying insertion through a narrow cannula. It should be noted that, as part of the different embodiments, Lambrecht et al. disclose (see Figures 40A-40D) said coiled spring as comprising an oval-shaped cross-section (see spring 154, having oval-shaped cross-section 198) in order to provide greater stability against rotation about a long axis of the spring (see column 25, lines 3-5).

For example, Perren et al. disclose (see Figures 1-5) an implant for location within an intervertebral space, which implant is formed of a self expanding material such as nickel titanium alloy (see column 2, line 40 to column 3, line 5) in order to allow introduction of the implant through a small opening into the intervertebral space by means of a delivery cannula (see Figure 4). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an implant for location

within an intervertebral space, which implant is formed of a self expanding material such as nickel titanium alloy, as taught by Perren et al., with the helical coil of Bagby, in order to allow introduction of the implant through a small opening into the intervertebral space by means of a delivery cannula.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740.

7. Claims 10, 15, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petit (WO 2002/09625 A1) in view of Walkenhorst et al. (US 6,726,722 B2).

Petit discloses the invention as claimed in claims 1-3, 7, 11, 12, 17, 50, and 51 (see 102(b) rejection above) except for particularly disclosing the helical spring as comprising a substantially barrel-shaped outline. However, this is well known in the art. For example, Walkenhorst et al. disclose a spinal implant comprising a substantially barrel-shaped outline (see Figures 1, 2, and 5) since a barrel-like cage "is an inherently stronger pressure vessel than a simple cylinder design", and in order for the implant to have a higher compressive strength, greater resistance to fatigue, higher yield load, and to promote a better anatomical fit between adjacent vertebrae (see column 3, line 35 to column 4, line 35). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a spinal implant comprising a substantially barrel-shaped outline, as

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taught by Walkenhorst et al., with the helical coil of Petit, since a barrel-like cage "is an inherently stronger pressure vessel than a simple cylinder design", and in order for the implant to have a higher compressive strength, greater resistance to fatigue, higher yield load, and to promote a better anatomical fit between adjacent vertebrae.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740.

8. Claims 10, 15, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagby (US 5,263,953 A) in view of Walkenhorst et al. (US 6,726,722 B2).

Bagby discloses the invention as claimed in claims 1-3, 7, 11, 12, 17, 50, and 51 (see 102(b) rejection above) except for particularly disclosing the helical spring as comprising a substantially barrel-shaped outline. It is noted Bagby disclose turns adjacent a middle of said spring have a height greater than turns of said spring adjacent and end of said helical spring (see column 5, lines 31-38). Further, this is well known in the art. For example, Walkenhorst et al. disclose a spinal implant comprising a substantially barrel-shaped outline (see Figures 1, 2, and 5) since a barrel-like cage "is an inherently stronger pressure vessel than a simple cylinder design", and in order for the implant to have a higher compressive strength, greater resistance to fatigue, higher yield load, and to promote a better anatomical fit between adjacent vertebrae (see column 3, line 35 to column 4, line 35). Therefore, it would have been obvious to a person

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having ordinary skill in the art at the time the invention was made to have combined the teaching of a spinal implant comprising a substantially barrel-shaped outline, as taught by Walkenhorst et al., with the helical coil of Bagby, since a barrel-like cage "is an inherently stronger pressure vessel than a simple cylinder design", and in order for the implant to have a higher compressive strength, greater resistance to fatigue, higher yield load, and to promote a better anatomical fit between adjacent vertebrae.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738